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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,721	02/15/2001	Arne Hengerer	P00,1220	2618
26574	7590	05/18/2006	EXAMINER	
SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473			GILLIGAN, CHRISTOPHER L	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/784,721

Applicant(s)

HENDERER ET AL.

Examiner

Luke Gilligan

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/1/06 has been entered.

***Response to Amendment***

2. In the amendment filed 3/1/06, the following has occurred: claims 1, 4, 5, 12, and 14 have been amended and claim 3 has been canceled. Now, claims 1, 2, and 4-15 are presented for examination, while claims 16-19 are withdrawn.

***Claim Objections***

3. Claim 8 is objected to because of the following informalities: It appears that claim 8 is inadvertently dependent on claim 6 rather than claim 7 due to the reference to "said up-to-date medical knowledge and patient data." Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 4-8, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al., U.S. Patent No. 6,383,150 in view of Lawrence et al., U.S. Patent No. 6,272,481.

6. As per claim 1, Stewart teaches a network expert system for automatic evaluation and quality control of medical point of care laboratory measurement data, comprising: a point of care measuring device disposed at a point of care which obtains point of care laboratory measurement data (see column 5, lines 59-65); a central expert system, disposed remote from said location of point of care, and a data link, selected from the group consisting of a data line and a data network, connecting said central expert system to said point of care measuring device (see column 6, lines 48-56); said central expert system being accessible by a treating physician via said data link to function as a virtual laboratory data collection and diagnostic system for acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data (see column 6, lines 57-61); and a central laboratory connected online to said expert system for automatically reporting back a listing to said treating physician of secondary examinations available for acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data to evaluate therapy results (see column 6, lines 64-65).

7. Stewart does not explicitly teach reporting secondary examinations available to make an evaluation available to said treating physician if an initial evaluation at said expert system of said point of care laboratory measurement data does not produce a definitive diagnosis. Lawrence teaches reporting secondary examinations available to make an evaluation available to a treating physician if an initial evaluation at an expert system of point of care laboratory measurement data does not produce a definitive diagnosis (see column 8, lines 21-40). It would

Art Unit: 3626

have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such follow up testing of laboratory measurement data into the system of Stewart. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of aiding in the accurate evaluation and treatment of specific symptoms (see column 4, lines 24-27 of Stewart).

8. As per claim 2, Stewart in view of Lawrence teach the system of claim 1 as described above. Stewart further teaches said point of care measuring device is disposed at a facility of a physician (see column 3, lines 49-62).

9. As per claim 4, Stewart in view of Lawrence teach the system of claim 1 as described above Stewart does not explicitly teach the central laboratory reports the results of the secondary examinations to the expert system and the expert system re-evaluates the point of care laboratory measurement data by using the results of the secondary examinations. However Lawrence further teaches this element (see column 8, lines 29-40). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such follow up testing of laboratory measurement data into the system of Stewart for the reasons given above with respect to claim 1.

10. As per claim 5, Stewart in view of Lawrence teach the system of claim 1 as described above. Stewart further teaches a request to the point of care is automatically made for providing a sample for the central laboratory (see column 6, lines 50-55).

11. As per claim 6, Stewart in view of Lawrence teach the system of claim 1 as described above. Stewart further teaches a plurality of sub-systems forming said central expert system connected to each other via a data network using data encoding (see Figure 1).

12. As per claim 7, Stewart in view of Lawrence teach the system of claim 1 as described above. Stewart further teaches said expert system includes a data bank containing up-to-date

Art Unit: 3626

medical knowledge and patient data and acts on said point of care laboratory measurement data using said medical knowledge and said patient data (see column 4, lines 6-19).

13. As per claim 8, Stewart in view of Lawrence teach the system of claim 7 as described above. Stewart further teaches said central expert system includes means for limiting access to said up-to-date medical knowledge and patient data only to authorized persons (see column 7, lines 63-35).

14. As per claim 12, Stewart teaches a networked expert system for automatic evaluation and quality control of medical point of care laboratory measurement data, comprising: a communications interface for receiving a message including a point of care laboratory measurement data (see column 5, lines 59-65); a central expert system including access to a data bank for examining the point of care laboratory measurement data (see column 6, lines 48-59); a data bank containing up-to-date medical knowledge and patient data (see column 5, line 65 – column 6, line 2); an input processor for receiving data comprising a diagnostic evaluation of the point of care laboratory measurement data and therapy concepts and background knowledge (see column 6, lines 57-59); and a distribution processor for forwarding the received diagnostic evaluation data and therapy concepts and background knowledge to a destination system (see column 6, lines 59-65).

15. Stewart does not explicitly teach assessing sufficiency of said point of care laboratory measurement data for preparing a definite diagnosis. However Lawrence teaches assessing sufficiency of point of care laboratory measurement data for preparing a definite diagnosis (see column 8, lines 21-40). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Stewart. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of aiding in the accurate evaluation and treatment of specific symptoms (see column 4, lines 24-27 of Stewart).

Art Unit: 3626

16. Claims 13-15 contain substantially similar additional limitations to those already addressed in claims 1, 2, and 4 and, as such, are rejected for similar reasons as given above.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al., U.S. Patent No. 6,383,150 in view of Lawrence et al., U.S. Patent No. 6,272,481 and further in view of Jachimowicz et al., U.S. Patent No. 5,763,862.

18. As per claim 9, Stewart in view of Lawrence teach the system of claim 7 as described above. Stewart does not explicitly teach at the location of said treating physician, a chip card reader which requires insertion of a chip card of an authorized user in order to authorize access to said central expert system. Jachimowicz teaches a chip card reader which requires insertion of a chip card of an authorized user in order to authorize access to said central expert system (see column 3, lines 44-48). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this data security means into the system of Stewart. One of ordinary skill in the art would have been motivated to incorporate this element for the purpose of enhancing security of sensitive data located at various locations (see column 3, lines 52-59 of Jachimowicz).

19. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al., U.S. Patent No. 6,383,150 in view of Lawrence et al., U.S. Patent No. 6,272,481 and further in view of Stevens et al., U.S. Patent No. 6,599,481.

20. As per claim 10, Stewart in view of Lawrence teach the system of claim 1 as described above. Stewart does not explicitly teach a container for obtaining a patient specimen having an electronically readable identifier thereon. Stevens teaches a container for obtaining a patient specimen having an electronically readable identifier thereon (see column 4, lines 1-12). It

Art Unit: 3626

would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Stewart. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of facilitating more efficient processing of handling operations within a laboratory (see column 4, lines 6-7 of Stevens).

21. As per claim 11, Stewart in view of Lawrence and Stevens teaches the system of claim 10 as described above. Stewart does not explicitly teach said electronically readable identifier is a bar code. Stevens further teaches said electronically readable identifier is a bar code (see column 4, lines 1-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Stewart for the reasons given above with respect to claim 10.

### ***Response to Arguments***

22. In the remarks filed 3/1/06, Applicant argues in substance that Barnhill fails to teach certain features of the claims as amended and that there is no motivation to combine Barnhill with the applied secondary references. In response to Applicant's arguments, it is respectfully submitted that the Examiner has now relied upon a new grounds of rejection in view of Stewart and Lawrence and, therefore, the arguments are now moot.

### ***Conclusion***

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.



Art Unit: 3626

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/11/06

  
C. LUKE GILLIGAN  
PATENT EXAMINER